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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/326,285	06/07/1999	JENNIE BIH-JIEN SHEN	BB-1137	4005

23906 7590 07/26/2004

E I DU PONT DE NEMOURS AND COMPANY
LEGAL PATENT RECORDS CENTER
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WILMINGTON, DE 19805

EXAMINER	
MCELWAIN, ELIZABETH F	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/326,285	SHEN, JENNIE BIH-JIEN	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *172-174 and 176* is/are pending in the application.

4a) Of the above claim(s) *172 and 173* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *174 and 176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 May 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2004 has been entered.

Election/Restrictions

2. Applicant's election without traverse of Group III, claims 174 and 176 in the reply filed on May 6, 2004 is acknowledged.

Claim Objections

3. Claim 176 is objected to because of the following informalities: the first line omits "of" after "method". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 174 and 176 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 174 and 176 are indefinite in that they are unduly alternative in that claim 174 recites "or" 20 times, and claim 176 recites "or" 22 times.

Claims 174 and 176 are also indefinite in the recitation of "consisting essentially of" with regard to nucleotide sequences, given that it is unclear what the claimed sequence would be, since this language could include any number of modifications to the sequence.

Claims 174 and 176 are further indefinite in the recitation of "altered corn oil phenotype" given that "altered" is a relative term. However, no basis for comparison has been set forth.

Claims 174 and 176 are indefinite in the recitation of "or part of" with regard to a sequence, since a part of a sequence could be as little as one nucleotide. Clarification is requested.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 174 and 176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous office actions.

7. Claims 174 and 176 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while teaching a method of feeding an animal with a corn grain that has an altered oil phenotype obtained from a corn plant transformed with pBN431, does not reasonably provide enablement for a method of feeding an animal with a corn grain obtained from a corn plant transformed with any of all or part of a nucleic acid encoding a corn delta-9 stearoyl ACP desaturase in either sense or antisense orientation and all or part of a nucleic acid encoding a corn delta-12 desaturase in either sense or antisense orientation. However, in order to enable the claimed invention, the plasmid pBN431 must be available to the public, given that it is unclear from the teachings in the specification exactly what sequences are comprised in said plasmid.

Since the sequence claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a sequence is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same plasmid sequence in each occurrence and it is not apparent if such a sequence is readily available to the public. If the deposit of this sequence is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the DNA will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the Commisioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

The specification only teaches a corn grain that has an altered oil phenotype obtained from a corn plant transformed with pBN431. The specification does not teach any other nucleic acid constructs comprising any of all or part of a nucleic acid encoding a corn delta-9 stearoyl ACP desaturase in either sense or antisense orientation and all or part of a nucleic acid encoding a corn delta-12 desaturase in either sense or antisense orientation that result in an altered oil phenotype. Therefore, if the deposit requirement for pBN431 is fulfilled, then the specification is enabled only for a method of feeding corn grain from a plant that has been

transformed with pBN431. The specification does not provide examples of any other combination of sequences, nor does the specification provide guidance with regard to which of sequences that are 90% identical to SEQ ID NO: 1 or which sequences that are part of either SEQ ID NO: 9 or 1 or sequences similar to SEQ ID NO: 1 could be used to produce the claimed result and with regard to how these plants or seeds would be screened.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

More specifically, identification of related sequences that will encode enzymes having a particular activity is particularly problematic in the enzymes involved in modifying fatty acids, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo

et al teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known to encode a particular activity, one cannot conclude that these other sequences also encode enzymes having said activity. In addition, De Luca teaches that modifying plant biosynthetic pathways by transforming plants with genes encoding enzymes involved in said pathway is highly unpredictable (see the paragraph bridging the columns on page 225N, for example), and that "on many occasions desired goals have been impossible to achieve" (see the last paragraph), and the modification of plant lipid composition by transforming a plant with said gene or a portion of said gene are highly unpredictable.

Thus, given the unpredictability of the effect on a plant of transforming a plant with sequences that encode a corn delta-9 stearoyl ACP desaturase in either sense or antisense orientation and all or part of a nucleic acid encoding a corn delta-12 desaturase in either sense or antisense orientation and that have as little as 90% identity to SEQ ID NO: 1; and given the lack of working examples of other combinations of similar sequences that have the same effect when transformed into a corn plant; and given the lack of guidance with regard to how to choose from the vast number of different possible combinations of sequences that are in sense or antisense, that are all or part of SEQ ID NO: 9 and that may be all or part of SEQ ID NO: 1 and as little as 90% identical to SEQ ID NO: 1; and given the lack of guidance with regard to how to screen any of these plants for an altered oil content, since it is unclear what results

would be expected; and given the breadth of the claims that encompass a vast number of possible sequence combinations, and use of said sequences to modify oil in corn; it would require undue experimentation by one skilled in the art to make and use the invention as broadly claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM